REMARKS

STATUS OF THE CLAIMS

Claims 1-40 and 43-51 were pending. As shown above, claims 3 and 47 have been amended as suggested by the Examiner to make the recitation "viral polypeptide or antigen" plural, as found in claim 2, from which they depend. In addition, claim 7 has been amended to depend from claim 6 (rather than claim 5), so that there is proper antecedent basis for the recitation "transcription promoter." Claim 27 has been amended from improper multiple dependent form. Claim 43 has been amended to depend from pending claim 29 rather than canceled claim 42. The amendments are formal in nature and are not made for reasons related to patentability. Thus, claims 1-40 and 43-51 are pending as shown above.

REJECTIONS WITHDRAWN

Applicants note with appreciation that all the rejections under 35 U.S.C. 1st paragraph (written description and enablement) have been withdrawn and the claims are acknowledged to be described and enabled by the specification as filed.

INFORMATION DISCLOSURE STATEMENT

Applicants acknowledge with appreciation return of the signed and initialed 1449 forms, indicating the references submitted in the IDSs submitted on June 17, 2005 and May 16, 2005 were considered.

PRIORITY

The Examiner asserts that claims 1-40 and 43-51 are not entitled to priority to any of 09/475,704; 60/114,495; and/or 60/152,195 on the grounds that these applications do not provide written support for SEQ ID NO:30-32. (Office Action, page 3).

Applicants respectfully disagree with the Examiner's assertion regarding priority. While a claim to the benefit of an earlier application requires that the disclosure in the earlier application comply with 35 U.S.C. § 112, first paragraph, compliance with 112, 1st paragraph does not necessarily require that the priority applications set forth *in ipsis verbis* the terms and language recited in the claims. *See, e.g., In re Lukach*, 169 USPQ 795, 796 (CCPA 1971). Indeed, the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *See, e.g., In re Edwards*, 196 USPQ 465, 469 (CCPA 1978). No such evidence has been provided.

In any event, Applicants submit that the skilled artisan would recognize that all three priority applications describe and enable production of synthetic polynucleotide sequences encoding an HIV polymerase (*see, e.g.,* page 4, lines 10-15, page 10, lines 21-26, Example 1 and Section 2.1.2 (starting on page 28) of 09/475,704; page 5, lines 6-14, page 14, lines 5-14; and page 38, lines 4-13 of 60/152,195; and page 36, lines 1-4 of 60/114,495).

Thus, Applicants submit that Applicants are entitled to an effective filing date of the 09/475,704; 60/114,495; and 60/152,195 applications.

CLAIM OBJECTIONS

Claims 27 and 28 were objected to as being in improper multiple dependent form. (Office Action, pages 3-4). Claims 43-46 were also objected to for depending from a cancelled claim. (Office Action, page 4).

Applicants submit that the foregoing amendments obviate the objections to claims 27, 28, and 43-46.

In addition, claim 47 was objected to for being separated from the claim from which it depends (claim 2). Applicants note that this claim will be renumbered upon indication of allowable claims.

35 U.S.C. § 112, 2ND PARAGRAPH

Claims 3, 7, 43-46 and 47 were rejected under 35 U.S.C. § 112, 2nd paragraph as allegedly indefinite. (Office Action, pages 4-5).

In particular, claims 3 and 47 were rejected as indefinite for reciting "viral polypeptide or antigen" in the singular when claim 2 (from which they depend) recites "one or more viral polypeptides or antigens." (Office Action, page 4). Applicants thank the Examiner for the suggested remedial language and have incorporated this language into claims 3 and 47 as shown by the foregoing amendments. Thus, the rejection of claims 3 and 47 can be withdrawn.

Claim 7 was rejected as indefinite for lack of antecedent basis for the term "transcription promoter." (Office Action, page 4). Applicants have amended claim 7 to depend from claim 6, thereby obviating this rejection.

Claim 43-46 were rejected as indefinite for depending from canceled claim 42. (Office Action, page 5). Applicants have amended claim 43 to depend from pending claim 29, thereby obviating this rejection.

Thus, the rejections under 35 U.S.C. § 112, 2nd paragraph have been obviated and withdrawal thereof is in order.

35 U.S.C. § 102

Claim 1 was rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 6,610,476 (hereinafter "Chang"). (Office Action, page 6). In addition, claims 1, 2, 5, 6, 8, 12, 13, 22, 23, 25 and 26 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,858,646 (hereinafter "Kung"). (Office Action, pages 6-7). Claims 1, 22, and 23 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO 98/26075 (hereinafter "Mauclere"). (Office Action, page 7). In support of these rejections it was asserted that (Office Action, page 5):

> The claimed invention reads on a nucleotide sequence encoding an HIV polypeptide, wherein the nucleotide sequence encoding the HIV polypeptide encode Pol polypeptide and comprises a nucleotide sequence having at least 90% identity to the sequence presented in SEQ ID NO:30-32 and a method fusing the expression cassette. The claimed invention reads on a nucleotide sequence encoding an HIV polypeptide, wherein the polypeptide as 70% sequence identity to the HIV polypeptide encoded by the nucleotide sequence set forth in SEQ ID NO:30-32.

The Examiner then asserted that, based on supposed similarity of the polypeptides encoded by the claimed polynucleotides, Chang, Kang and Mauclere somehow teach "a nucleic acid sequence encoding an HIV Pol polypeptide comprising a nucleotide sequence having at least 90% sequence [identity] to the sequence presented in SEQ ID NO:30-32." (Office Action, page 6).

Because Chang, Kang and Mauclere do not disclose polynucleotide sequence having 90% identity to SEQ ID NOs:30, 31 or 32, the rejection cannot be sustained.

Anticipation in the pending case is not determined relative to the polypeptide encoded by the claimed polynucleotide sequences. The claims are directed to polynucleotide sequences having at least 90 percent identity (at the nucleotide level) to SEQ ID NOs:30-32. Accordingly, the claims can only be anticipated by polynucleotide sequences falling within the claimed scope -- here, 90% identity to SEQ ID NOs:30, 31 or 32. In other words, the single reference cited by the Office must disclose each and every element of the claims. *Hybritech v. Monoclonal Antibodies,* 231 USPQ 81 (Fed. Cir. 1986). Moreover, the single source must disclose all of the claimed elements arranged as in the claims. *See, e.g., Richardson v. Suzuki Motor Co.,* 9 USPQ2d 1913 (Fed. Cir. 1989). The law requires identity as between the prior art disclosure and the invention. *See, e.g., Kalman v. Kimberly-Clark Corp.* 218 USPQ 781 (Fed. Cir. 1983), *cert. denied*, 484 US 1007 (1988).

In the instant case, none of the cited references disclose nucleotide sequences having 90% identity to any of SEQ ID NOs:30, 31 or 32. Rather, the cited reference disclose wild-type HIV polynucleotide sequences, which do not exhibit the requisite 90% sequence identity at the polynucleotide level.[1] It is improper for the Examiner to disregard the percent nucleotide identity limitation and to read an unrecited (and undisclosed) limitation into the claims (70% sequence identity at the polypeptide level).

When properly read for what they disclose about polynucleotides, it is clear that Chang, Kang and Mauclere disclose only wild-type HIV Pol-encoding sequences that do not exhibit 90% identity to the claimed reference sequences. Such polynucleotides do **not** fall within the scope of the claims. Nor do they "read on" polypeptides having 70% identity to the polypeptide encoded by the claimed sequences. Indeed, Chang's, Kang's and Mauclere's wild-type polynucleotide sequences that exhibit less than 90% identity to SEQ ID NOs:30, 31 or 32 are specifically **excluded** by the language requiring that the claimed polynucleotide exhibit at least 90% sequence identity to the polynucleotides of SEQ ID NOs:30, 31 or 32.

Sequence identity that **may** exist as between polypeptides encoded by the claimed sequences and polypeptides encoded by Chang, Kang and Mauclere is irrelevant to patentability of the pending claims. The relevant question is whether these references disclose a **polynucleotide** exhibiting 90% identity to SEQ ID NOs:30, 31 or 32, as claimed. These references clearly contain **no** such disclose and, accordingly, cannot anticipate the pending claims.

35 U.S.C. § 103

Claims 1, 2 and 3 were rejected under 35 U.S.C. § 103 as allegedly obvious over Kang in view of Rovinski. (Office Action, pages 8-9). Claims 1 and 4 were rejected as allegedly obvious over Kang in view of U.S. Patent No. 5,738,852. (Office Action, pages 9-10). Claims 1, 5 and 6 were rejected as allegedly obvious over Kang in view of U.S. Patent No. 6,489,542. (Office Action, pages 10-11). Claims 1, 5 and 7 were rejected as allegedly obvious over Kang in view of U.S. Patent No. 6,489,542 and in further view of U.S. Patent No. 5,830,697 or 6,391,632. (Office Action, pages 11-12). Claims 1, 8-12 and 16-21 were rejected as allegedly obvious over Kang in view of the ATCC catalog. (Office Action, pages 12-13). Claims 1, 8 and 14 were rejected as allegedly obvious over Kang in view of the U.S. Patent No. 5,470,720. (Office

[1] Although not required, Applicants have attached an alignment as between SEQ ID NO:30, 31, 32 and the Pol-encoding portions of SEQ ID NO:4 of Chang to illustrate the lack of 90% identity. Indeed, whereas SEQ ID NOs:30-31 and 32 are 99% identical to one another, Chang, at best, exhibits 60% identity to any of the three claimed reference sequences. Similarly, as shown in another attached alignment, the nucleotide sequences disclosed in Kang exhibit, at best, 60% identity to reference SEQ ID NO:30.

Action, pages 13-14). Claims 1, 8 and 15 were rejected as allegedly obvious over Kang in view of Adams et al. (Office Action, pages 14-15). Claims 1, 22, 29, 30-32, 34 and 38-40 were rejected as allegedly obvious over Kang in view of Tobin et al. (Office Action, pages 15-17). Claims 1, 22, 29, 30, 32 and 33 were rejected as allegedly obvious over Kang in view of Tobin et al. and in further view of U.S. Patent No. 5,622,705. (Office Action, pages 17-18). Claims 1, 22, 29, 30, 32 and 35 were rejected as allegedly obvious over Kang in view of Tobin et al. and in further view of Kafri et al. (Office Action, pages 18-19). Claims 1, 22, 30, 36 and 37 were rejected as allegedly obvious over Kang in view of Tobin et al. and in further view of Lai et al. (Office Action, pages 19-20). Claims 1 and 22-24 were rejected as allegedly obvious over Kang in view of Shiver et al. (Office Action, pages 20-21).

For the reasons noted above, Kang does not describe, demonstrate or suggest **polynucleotides** having at least 90% identity to SEQ ID NOs:30, 31 or 32 as claimed. Rather, Kang relates to wild-type HXB2 polynucleotide sequences that exhibit less than 90% identity to SEQ ID NOs:30, 31 or 32 (see, attached alignment). As such, there is no combination of Kang with any of the secondary references that can support an obviousness rejection.

It is well settled that claims to polynucleotide sequences are not obvious in view of a disclosure of protein sequences encoded by the polynucleotides. *See, e.g., In re Bell* 26 USPQ2d 1529 (Fed. Cir. 1993). It is also axiomatic that an obviousness rejection of polynucleotide claims cannot be based on a combination of a reference teaching a protein encoded by the polynucleotides and a generalized reference teaching how to isolate or manipulate DNA. *In re Deuel* 34 USPQ2d 1210 (Fed. Cir. 1995).

Accordingly, Kang's disclosure of wild-type HXB2 polynucleotide sequences cannot render obvious claims directed to synthetic polynucleotide sequences that exclude such wild-type sequences, regardless of the polypeptide encoded by these polynucleotides. Thus, the claims are novel and non-obvious over Kang, either alone or in light of any of the secondary references (including generalized knowledge regarding manipulation of polynucleotides). Withdrawal of the rejections under section 103 is, therefore, in order.

PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

Applicants request the provisional double patenting rejection over 10/190,435 be held in abeyance until indication as at allowable claims is received in one of the applications.

CONCLUSION

In view of the foregoing amendments, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §1.16, §1.17, and §1.21, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648, referencing Atty. Docket No. 2302-1631.20.

Please direct all further written communications regarding this application to:

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Respectfully submitted,

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